LABEL IN PART: (Typical specimens on repacked drugs) "No. 11 for Sugar Diabetes Take two tablespoonfuls three times per day," "No. 12 one teaspoonful every three hours," "No. 14 Cancer Liniment Saturate a cloth and apply twice a day," and "No. 45 Kidney Medicine One teaspoonful in a glass of water. Dose, ⅓ morning, noon and night."

ACCOMPANYING LABELING: An unknown quantity of loose, printed and typed labels intended for use on the repacked drugs.

RESULTS OF INVESTIGATION: The repacked drugs had been prepared by W. H. McConnell, by grinding a portion of the crude botanical drugs into a powder and packing into cardboard boxes of 2-oz. and 8-oz. sizes; by grinding to a powder and capsulating the crude drugs, and then packaging the capsules in boxes of 60 or 100 capsules; and by mixing the crude drugs and cooking them with water, and then bottling the liquid extracts into 2-, 6-, 12-, and 32-ozs. btls.

LIBELED: On or about 5–6–58, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, a portion of the labels of the articles contained false and misleading claims for the treatment of cancer, diabetes, sinus infection, "flu," rheumatism, and other serious diseases for which the articles would not be an adequate and effective treatment; 502(b)(2)—none of the labels of the articles bore any statement of the quantity of contents contained therein; 502(e)—the labels of the articles failed to bear (1) the common or usual name of the article, and (2) the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, for example, eight of the liquid medicines were intended to be used as "blood purifiers," and their individual labels failed to state the purpose for which they were to be used, and item "No. 12" was intended for use as a "strengthener and growth dissolver," and its label gave no indication for use.

DISPOSITION: 6–10–58. Default—some of the drugs were delivered to the Food and Drug Administration and the remainder was destroyed.

5625. Epsom salt. (F.D.C. No. 41525. S. No. 6–979 P.)

QUANTITY: 210 cases, 12 boxes each, at Providence, R.I.

SHIPPED: 4–9–58, from Boston, Mass., by Atlantic Salt & Chemical Co. (also known as Atlantic Salt Co.).

LABEL IN PART: (Box) "Five Pounds Atlantic Clipper Epsom Salt U.S.P."

LIBELED: 4–21–58, Dist. R.I.

CHARGE: 502(a)—the label of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for biliousness and other digestive disorders; and 502(f)(2)—the article was essentially a laxative, and its labeling failed to bear a warning that frequent or continued use may result in dependence on laxatives to move the bowels.

DISPOSITION: 6–24–58. Consent—claimed by Atlantic Salt Co. and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5626. Posterior pituitary injection. (F.D.C. No. 41625. S. No. 64–360 M.)

QUANTITY: 4 ctns., 100 ampuls each, at Pittsburgh, Pa.

SHIPPED: 11–11–57, from Tuckahoe, N.Y., by Burroughs Wellcome & Co., Inc.

LABEL IN PART: (Ctn. and ampul) "Infundin Posterior Pituitary Injection * * * 1 cc. (10 U.S.P. Units)."

LIBELED: 3–14–58, W. Dist. Pa.

CHARGE: 501(b)—the strength of the article, when shipped, fell below the standard for the article set forth in the United States Pharmacopeia; and 502(a)—the label statement "Posterior Pituitary Injection * * * 1 cc. (10 U.S.P. Units)" was false and misleading as applied to the article, the potency of which was substantially less than 10 U.S.P. posterior pituitary units per cubic centimeter.

DISPOSITION: 6–18–58. Default—destruction.

5627. Pituitary posterior injection. (F.D.C. No. 41612. S. No. 83–304 M.)

QUANTITY: 3 cases, containing a total of 621 vials, at New Castle, Ind.

SHIPPED: 9–10–57 and 9–19–57, from Berkeley, Calif., by Borden Laboratories, Inc.

RESULTS OF INVESTIGATION: Individual vial labels to be affixed by the dealer read in part "10CC Posterior Pituitary Injection * * * 20 U.S.P. Units per CC." Also accompanying the article was a loose label which read in part "Borden Laboratories, Inc. * * * 500 Vials Posterior Pituitary Extract 20 Units U.S.P. ML."

LIBELED: 3–20–58, S. Dist. Ind.

CHARGE: 501(b)—the strength of the article, when shipped, fell below the standard for posterior pituitary extract set forth in the United States Pharmacopeia; and 502(a)—the label statements "Posterior Pituitary Extract 20 Units U.S.P. ML." and "10 CC Posterior Pituitary Injection * * * 20 U.S.P. Units Per CC" were false and misleading as applied to the article, the potency of which was substantially less than 20 U.S.P. posterior pituitary units per milliliter or per cubic centimeter.

DISPOSITION: 6–27–58. Default—destruction.

5628. Amphetidisin-10 capsules. (F.D.C. No. 41577. S. No. 37–724 P.)

QUANTITY: 35 1,000-capsule btls. at St. Louis, Mo.

SHIPPED: 10–17–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: "1000 Capsules Amphetidisin-10 Timed Disintegration Capsules Dextro-Amphetamine Sulfate 10 Mg. Each Capsule Contains 10 Mg. of Dextro-Amphetamine Sulfate in a Special Base that Provides for Timed Disintegration of the Contents throughout a Period of about 6–10 Hours."

RESULTS OF INVESTIGATION: Analysis showed that the article contained the labeled amount of dextro-amphetamine sulfate of which 88 percent was released within 2 hours.

LIBELED: 2–13–58, E. Dist. Mo.

CHARGE: 501(c)—the quality of the article, when shipped, differed from that which it purported or was represented to possess in that it failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the labeled statement "Timed Disintegration Capsules * * * Each Capsule Contains 10 Mg. of Dextro-Amphetamine Sulfate in a Special Base that Provides for Timed Disintegration of the Contents throughout a Period of about 6–10 Hours" was false and misleading.

DISPOSITION: 3–12–58. Default—destruction.